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**Summary of Safety and Effectiveness****OCT 17 2002**

**Submitter:** Zimmer, Inc.  
P.O. Box 708  
Warsaw, IN 46581-0708

**Contact Person:** Stephen H. McKelvey  
Manager, Regulatory Affairs  
Telephone: (574) 372-4944  
Fax: (574) 372-4605

**Date:** September 23, 2002

**Trade Name:** *NexGen*<sup>®</sup> Complete Knee Solution Cruciate  
Retaining (CR)-Flex Femoral Components

**Common Name:** Total Knee Prosthesis

**Classification Name  
and Reference:** Knee joint patellofemorotibial polyethylene/  
metal/polyethylene semiconstrained cemented total  
knee prosthesis - 21 CFR § 888.3560

**Predicate Devices:** *NexGen* CR knee, manufactured by Zimmer,  
K933785, cleared January 30, 1995 and the *NexGen*  
LPS-Flex knee, manufactured by Zimmer,  
K991581, cleared July 30, 1999.

**Device Description:** The *NexGen* CR-Flex femoral components are part  
of the Zimmer Flex-series of semiconstrained,  
nonlinked condylar knee prostheses that are  
designed to have a maximum active flexion of 155  
degrees.

**Intended Use:** This device is indicated for:

Patients with severe knee pain and disability due  
to rheumatoid arthritis, osteoarthritis, traumatic  
arthritis, polyarthritis, collagen disorders and/or  
avascular necrosis of the femoral condyle, post-  
traumatic loss of joint configuration  
(particularly when there is patellofemoral  
erosion, dysfunction, or prior patellectomy), and  
moderate valgus, varus, or flexion deformities.

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- The salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.

This device is intended for cemented use only

Specific uses with CR-Flex femorals:

- Provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range.
- The CR-Flex femoral is designed for use with a functional posterior cruciate ligament and when load bearing range of motion (ROM) is expected to be less than or equal to 155 degrees.

**Comparison to Predicate Device:**

Except for modifications to allow flexion to 155 degrees, CR-Flex femoral components are identical to the predicate device. The modifications do not change the intended use or the fundamental scientific technology. The device is packaged and sterilized using the same materials and processes

**Performance Data (Nonclinical and/or Clinical):**

**Non-Clinical Performance and Conclusions:**

Performance testing completed as part of the design assurance procedure demonstrated that this device is safe and effective and substantially equivalent to the predicate device.

**Clinical Performance and Conclusions:**

Clinical data and conclusions were not needed for this device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 17 2002

Mr. Stephen H. McKelvey  
Manager, Regulatory Affairs  
Zimmer, Inc.  
P.O. Box 708  
Warsaw, Indiana 46581-0708

Re: K023211  
Trade/Device Name: NexGen® Complete Knee Solution Cruciate Retaining Flex Femoral  
Component  
Regulation Number: 888.3560  
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer, semi-constrained  
Cemented prosthesis  
Regulatory Class: II  
Product Code: JWH  
Dated: September 23, 2002  
Received: September 26, 2002

Dear Mr. McKelvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

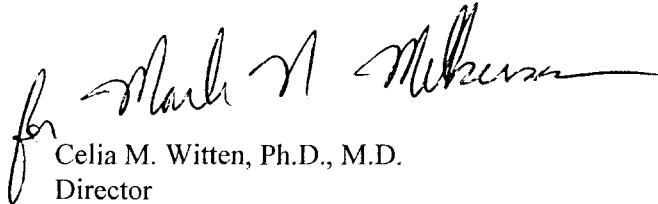
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Stephen H. McKelvey

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4649. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

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510(k) Number (if known): K023211

### Device Name:

NexGen® Complete Knee Solution Cruciate Retaining (CR)-Flex Femoral Components

### Indications for Use:

This device is indicated for:

- Patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders and/or avascular necrosis of the femoral condyle, post-traumatic loss of joint configuration (particularly when there is patellofemoral erosion, dysfunction, or prior patellectomy), and moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.

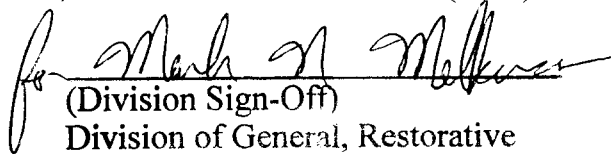
This device is intended for cemented use only

Specific uses with CR-Flex femorals:

- Provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range.
- The CR-Flex femoral is designed for use with a functional posterior cruciate ligament and when load bearing range of motion (ROM) is expected to be less than or equal to 155 degrees.

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K023211

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)